

### **REMARKS**

In the Office Action of May 30, 2002, Claims 18 and 35 - 43 were rejected. Claims 17 and 28 - 34 are withdrawn from consideration. No claim was allowed. In response, Claims 37 and 39 - 41 are canceled without prejudice or disclaimer, Claims 18, 42 and 43 are amended and new Claims 44 - 48 are added to the application. Reexamination and reconsideration are respectfully requested in view of the foregoing amendments and the following remarks.

### **Request for Entry of Amendments and Declarations**

Claims 18, 42 and 43 are amended herein to provide that the protein of the protein/phospholipid complex or protein hydrolyzate/phospholipid complex is wheat or soybean protein. These amendments are submitted to overcome a rejection that the generic "plant protein" is not enabled by the specification. The Examiner has already indicated that the specific proteins listed in the specification are enabling. New Claims 44 - 48 are added to provide independent claims 42 and 43 with a set of dependent claims such as is already provided for independent. Claim 18. Therefore, it is respectfully submitted that the amendments and new claims do not raise new issues for consideration.

The Declaration of Miho Takada is submitted to address issues raised by the examiner by the Declarations submitted in the previous response.

Entry of the amendments and new claims, and consideration of the Declaration of Miho Takada are therefore respectfully requested.

**Rejection of Claims 1 - 27 under 35 U.S.C. §112, first paragraph**

Claims 18 and 35 - 43 are rejected under 35 USC 112, first paragraph, on the alleged grounds that the specification is enabling only for specific proteins listed in the specification and the cholesterol lowering effect of the complex, but does not provide enablement for generic "plant proteins".

In response, Claims 18, 42 and 43 are amended to recite "wheat proteins or soybean proteins", for which enablement is provided in Examples 1 to 4 of the specification.

Accordingly, it is respectfully submitted that the rejection under 35 U.S.C. §112, first paragraph, are thereby overcome.

**Rejection of Claims 18 and 35 - 43 under 35 U.S.C. §103(a) over Sugano (J. Nutr., 1990) or Sugano (Atherosclerosis, 1988) by themselves or in combination with Williams**

Claims 18 and 35 - 43 were rejected under 35 U.S.C. §103(a) as obvious over Sugano (J. Nutr., 1990) or Sugano (Atherosclerosis, 1988) by themselves or in combination with Williams (Perspectives in Biology and Medicine, 1984). The Examiner alleged that these references teach the effectiveness of soybean protein-phospholipid complexes in lowering cholesterol levels.

This rejection is traversed. Both of the Sugano publications focus on the effect of reducing serum and liver cholesterol by an undigested high molecular fraction of soybean protein obtained after microbial protease digestion. The publications do not teach any benefit of a protein/phospholipid complex or protein hydrolyzate/ phospholipid complex for lowering cholesterol or improving cholesterol

metabolism. For example, the authors state "Also uncertain is the effect of components other than the peptides on the serum cholesterol level" (Sugano, Atherosclerosis, 1988, page 120, left column, lines 35 - 37.) and that "[t]he mechanism underlying the hyposcholseterolemic effect of soybean protein in relation to animal protein, particularly casein, is not fully understood (Sugano, J. Nutr., 1990, page 984, right column, lines 49 - 51.). Williams only teaches the effect of intravenously administered lecithin (phospholipid) on cholesterol removal. The references alone or combined do not teach or suggest a method of administering a protein/phospholipid complex or protein hydrolyzate/ phospholipid complex, or even of a simple mixture of protein and phospholipid for lowering cholesterol or improving cholesterol metabolism, particularly in the amounts provided in Claims 18, 42, and 43.

The Examiner further alleged that it would have been obvious to alter the amounts of the phospholipids in the phospholipid-soy complex in Sugano, with the expectation of obtaining the best possible results, since Williams teaches that phospholipids by themselves are effective in cholesterol removal. This allegation is respectfully traversed. As a rebuttal of any prima facie case of obviousness, Applicants submit a Declaration of Miho Takada dated November 25, 2002, showing the effect of protein/phospholipid complex in lowering cholesterol levels. As shown in Figures 1 and 2 of Experiment I in the Declaration, the complex in which the content of bound phospholipid is from 20 to 50 wt% has a significant effect of lowering cholesterol in serum and liver, compared with a complex in which the content of bound phospholipid is 10 wt% or less. This significant effect obtained by a complex

in which the content of bound phospholipid is from 20 to 50 wt% is neither disclosed nor suggested by the Sugano references or Williams.

Accordingly, it is respectfully submitted that Claims 18 and 35 - 36, 38 and 42 - 43 are not obvious over the Sugano references or Williams, alone or in combination, or, in the alternative, that any case of prima facie obviousness is overcome by the evidence provided in the declaration submitted herewith.

**Rejection of Claims 18 and 35 - 43 under 35 U.S.C. §103(a) over Sirtori in combination with Williams**

Claims 18 and 35 - 43 were rejected under 35 U.S.C. §103(a) as obvious over Sirtori (Ann. Nutr. Metab. 1985) in combination with Williams. The Examiner alleges that Sirtori teaches the effectiveness of lecithinated soy proteins in lowering cholesterol and that Williams teaches the effectiveness of phospholipids in cholesterol removal.

In response to the applicants' previous showing of nonobviousness and unexpected results obtained by a protein hydrolyzate/ phospholipids complex containing 20 - 50% of bound phospholipid, the Examiner alleged that the declaration submitted with the response of March 11, 2002 was not persuasive because studies were conducted with phospholipase digested complex and not on undigested product and that there are no values for lecithin itself to determine whether the values are additive or synergistic. In response, and in rebuttal of any prima facie case of obviousness, Applicants submit a Declaration of Miho Takada dated November 25, 2002, showing the synergistic effect of protein/phospholipid complex in lowering cholesterol levels. As shown in Figures 3 and 4 of Experiment II

in the Declaration, the complex produced by binding protein to undigested phospholipid has the unexpected effect of lowering cholesterol level, especially in the liver, compared with the protein by itself, the phospholipid by itself, or the simple mixture of the protein and undigested phospholipid. This significant effect obtained by a complex in which the content of bound phospholipid is from 20 to 50 wt% is neither disclosed nor suggested by Sirtori or Williams, alone or in combination.

Accordingly, it is respectfully submitted that any case of obviousness is overcome by the showing herein, and that the rejection under 35 U.S.C. §103(a) for obviousness over Sirtori and Williams is thereby overcome.

### **Conclusion**

In view of the foregoing amendments and remarks, it is respectfully submitted that Claims 18, 35, 36, 38, 42, 43 and new claims 44 - 48 are in condition for allowance. Favorable reconsideration is respectfully requested.

Should the Examiner believe that anything further is necessary to place this application in condition for allowance, the Examiner is requested to contact applicants' undersigned attorney at the telephone number listed below.

Kindly charge any additional fees due, or credit overpayment of fees, to  
Deposit Account No. 01-2135 (506.35379CC2).

Respectfully submitted,  
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Attachments:  
Declaration Pursuant 37 CFR 1.132 of  
Miho Takada